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The imaging technology of Dynamic Functional Optical Mammoscopy (DFOM) has been used to scan patients scheduled for biopsy of breast lesions. These patients were scheduled for core or excisional breast biopsy on the basis of equivocal mammographic and ancillary clinical findings within ACR BI-RADS™ categories 3 or 4. Analysis of test results of 47 patients shows that the DFOM detected cancer in nine of the 11 patients in whom biopsies confirmed malignant lesions giving a sensitivity of 82%. DFOM also correctly identified 24 of 36 benign lesions giving a specificity of 67%. In clinical practice, the adjunctive use of DFOM would have decreased the percentage of biopsies that turn out to be benign from 36/47 (77%) to 12/47 (26%). The negative predictive value, the chance that a negative DFOM result truly indicates a benign lesion, was 24/26 (92%).

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Introduction

The imaging technology of Dynamic Functional Optical Mammoscopy (DFOM) is a breast scan based upon transmission/absorption of infrared light, which measures the dynamic patterns of breast reactivity of various physiological states in response to soft pressure. DFOM produces a functional rather than a morphological image and the dynamic pattern of tissue reactivity after mild compression is charted. Pilot study results suggested that this innovative DFOM imaging technique has the potential to determine which of the mammographically and clinically indeterminate lesions are benign vs. carcinoma and distinguish those lesions thereby avoiding biopsy. The purpose of the study reported here is to extend the preliminary results of the pilot study at Columbia Presbyterian Medical Center, using DFOM between mammography and biopsy to further evaluate the efficacy of DFOM in evaluation of breast lesions, using biopsy results to confirm diagnosis.

Body

A total of 117 patients scheduled for biopsy were scanned with the identical protocol between June 1, 2000 and September 30, 2000. The study was performed on women scheduled for core or excisional breast biopsy on the basis of equivocal mammographic and ancillary clinical findings within ACR BI-RADS™ categories 3 or 4. Women who met the selection criteria were enrolled from the normal caseload from both screening and diagnostic mammography. Each woman signed an informed consent prior to being scanned.

The scan procedure required approximately 5 minutes. During examination, the breast was placed in the soft breast holder of the system. The breast was then softly compressed by a thin transparent silicone rubber membrane using an applied pressure of approximately 10 mm Hg. For each scan, the breast was symmetrically centered on the illuminator. When the breast was correctly positioned, illumination adjustment and image recording took place following the requirements of the pressure profile.

Optical illumination was provided by an array of red light emitting diodes (LEDs) attached to the bottom surface of the soft breast holder. Light transmitted through the breast was recorded as a temporal sequence for approximately 30 seconds by a highly sensitive digital CCD camera. The image sequences were accumulated in digital memory and processed by proprietary software to accentuate differences in the temporal variations of intensity between normal/benign and malignant tissue.

Each woman was scanned by a trained technologist prior to biopsy. The scans were read by an experienced reader trained in interpreting the scans. Results were reported as either a recommendation for biopsy or a recommendation that the woman be sent to interval follow-up.

Recommendations on the basis of DOFM were compared to pathology reports of malignant or benign which were used as the gold standard. Sensitivity, specificity, and negative predictive value were calculated.

Table 1 gives the patient accounting for the 117 patients reported on during this period.

TABLE 1 – Patients Scanned June 1 – September 30, 2000

Excluded patients*	= 40
Unacceptable scans**	= 20
Scans to be interpreted	= 10
Interpreted scans	= 47
Total scans performed	= 117

*Patients who did into meet the selection criteria for the development study protocol.
**Patients whose scans were not acceptable to be interpreted.

Table 2 presents the reasons for scans determined to be unacceptable.

TABLE 2 – Unacceptable Scans	
Lesion sub areolar or located where it cannot be properly illuminated	= 5
Inadequate illumination in area of pathology	= 6
Device related	= 4
Incorrect illumination	= 2
Not enough breast tissue in holder	= 2
Excessive patient movement	= 1
Total	= 20

Below, Table 3 lists reasons for excluding from our study selected patients.

TABLE 3 – Excluded Patients	
Lesion sub areolar or located where it cannot be properly illuminated	= 12
Previous surgery in ipsilateral breast	= 9
BI-RADs 5 lesion	= 4
Post-menopausal with palpable lesoin	= 3
Relevant record(s) not available oat site of review	= 2
Small breast that could not be properly positioned	= 2
Patient could not remain still	= 1
Biopsy of ipsilateral breast within 3 months	= 1
Biopsy to be performed at another facility	= 1
Not recorded	= 5
Total	= 40

Table 4 presents patient demographics of race and age.

TABLE 4 – Patient Demographics

Race	
White	= 58
African American	= 5
Hispanic White	= 34
Hispanic Black	= 16
Asian	= 2
Other	= 2
Total	= 117

AGE: Average = 56
Range = 35-82

Table 5 presents the results of scan interpretation.

TABLE 5 – Results of 47 Patients Scheduled for Biopsy

		Pathology		
		Malignant	Benign	Total
DFOM Recommendation	Biopsy	9	12	21
	Interval Follow-Up	2	24	26
	Total	11	36	47

Sensitivity: 9/11 (82%)
Specificity: 24/36 (67%)
Negative Predictive Value (NPV): 24/26 (92%)

The analysis of test results on the 47 patients with interpreted scans shows that the DFOM detected cancer in 9 of the 11 patients in whom biopsies confirmed malignant lesions ("true positives"). This results in a sensitivity of 82%. The system also correctly identified 24 of 36 benign lesions ("true negatives"). In other words, the specificity of the DFOM is 24/36 (67%).

Key Research Accomplishments

Below we summarize our accomplishments in the context of the original Statement of Work, as described in the proposal.

TASK 1. Develop substructure for implementing study (months 1-3).

(a) Obtained Institutional Review Board (IRB) Approval, including patient consent form.

(b) Trained three consecutive research associates in protocol and procedures:
Patricia Ogiliva 11/30/98 – 6/3/99,
Homyra Hadavand 6/14/99 – 11/30/99 and
Behnaz Mesbah 12/13/99 – 8/31/01.

(c) Develop database program to enable data entry and to allow compilation of results.

TASK 2. Develop a database of DFOM dynamic imges and signatures of various pathologic lesions (months 3-34).

(a) Recruited patients undergoing evaluation of lesions to have DFOM scan prior to tissue sampling or biopsy.

(b) Correlated DFOM information evaluated for acquired dynamic images and signature types with pathologic lesion by type, grade (Bi-Rads scale) and size. Compared appearance with parenchymal density.

TASK 4. Interim analyses (months 12-26).

(a) Interim analysis has been presented in this report for the fist phase of the study, and is currently being collected for analysis in the next annual report.

Reportable Outcomes

The effectiveness of the DFOM in discriminating between benign and malignant breast lesions has been further evaluated and the preliminary results have been corroborated.

Conclusions

While the number of patients reported on is small, the indications of effectiveness are very encouraging. The results reported above indicate that the adjunctive use of the DOFM in clinical practice would have decreased the percentage of biopsies that turn out to be benign from 36/47 (77%) to 12/47 (26%). The negative predictive value, the chance that a negative DFOM result truly indicates a benign lesion, is 24/26 (92%).

Thus, we are encouraged by these early findings. We will continue to accrue patients and analysis data during the next phase.

References

None.

Appendices

Summary Tables of Scanned Patients - First Year of Study

CPMC

	Patient ID	Protocol	Press. P	Acceptable	Blind	Adjunct	BiRads	Unblind	Biopsy	S.conf
1	19980915A-L	post-biopsy	E	NO - NC						y
2	19980915A-R	post-biopsy	E	NO - NC						y
3	19981001A R	8408	E	YES			3	TN	FA + FC, non-proliferative	y
4	19981001B L	8408	E	YES			1	TN	Focal fibrosis, focal fibrocytic chg	y
5	19981005A R	8408	E	YES			3	TN	microfibroadenoma	y
6	19981008A R	8408	D	YES			3	TN	FC, epithelial hyperplasia, f. atypia	y
7	19981013A L	8408	D	YES			4	TP	DCIS, multifocal, cribif. NG2-S0	y
8	19981013B R	8408	D	YES			4	TN	FC, non-proliferative	y
9	19981014A L	8408	E	YES			4	TN	FC with microcalcifications	y
10	19981022A L	8408	E	NO - NB						
11	19981023A	volunteer	G1	NO - NC						
12	19981023B L	8408	E	YES	TP	TP	5	TP	mxd:DCIS, ID, lobular SIII	y
13	19981028A L	8408	H	YES	TN	TN	4	TN	FC	y
14	19981110A L	post-biopsy	H	NO - NC						
15	19981110B	volunteer	H	NO - NC						
16	19981124A L	8408	H	YES	FN	TP	5	TP	ID and in situ ductal carcinoma	y
17	19981124B L	8408	H	YES	TN	TN	3	TN	FC, FA	y
18	19981125A L	8408	G1	YES	TN	TN	3	TN	FC, proliferative , no atypia	y
19	19981125B R	8408	G1	YES	TN	TN	3	TN	FF, FC, Intraductal papilloma	y
20	19981130A	8408	G1	PENDING					*fna only….*	
21	19981130B - L-SAR	8408	G1	PENDING					*just had biopsy (5-21-99)*	
22	19981201A R	8408	G1	YES	TP	TP	4	TP	DCIS+FC (proliferative. +atypia	y
23	19981202A L	8408	G1	YES	TN	TN	2	TN	FF, aprocrine cyst	y
24	19981202A-R	8408	G1	YES	INDET.	FP	2	FP	FF, lobular hyperplasia, adenosis	y
25	19981202B L	8408	G1	YES	FN	FN	5	FN	Invasive ductal +focal DCIS	y
26	19981202B-R	8408	G1	YES	FP	FP	3	FP	FF, epithelial hyperplasia	y
27	19981207A R	8408	G1	YES	TN	TN	3-4A	TN	FC+FAH	y
28	19981207B R	8408	G1	YES	TN	TN	3	TN	Adenosis, fibrosis	y
29	19981209A L	8408	G1	YES	TN	TN	3	TN	FC, FF	y
30	19981209B L	8408	G1	YES	TN	TN	2	TN	FD, Intraductal papilloma	y
31	19981216A L	8408	G1	YES	INDET.	FN	5	TP	ID G2-3 focal tubular features.	y
32	19981221A	8408	G1	YES	TN	TN	3	TN	FC + microcalc.	y
33	19981223A L	8408	G1	YES	TN	TN	3	TN	FC	y
34	19990104A R	8408	G1	NO-WP						y
35	19990104B L	8408	G1	YES	TN	TN	3	TN	FC	y
36	19990106A R	8408	S3	YES	TN	TN	3	TN	FA, FC, FF,	y
37	19990106B R	8408	S2	YES	TN	TN	4A	TN	FF+OSCIFICATION	y
38	19990106C L	8408	G1	YES	TP	TP	5	TP	ID (NOS) poorly differentiated	y
39	19990111A L	8408	G1	YES	TN	TN	3	TN	FC	y
CP	Patient ID	Protocol	Press. P	Acceptable	Blind	Adjunct	BiRads	Unblind	Biopsy	S. conf

40	19990111B R	8408	S3	YES	TN	TN	3	TN	Adenosis	y
41	19990112A L	8408	G1	NO - WP						y
42	19990113A	8408	G1	NO - WP						
43	19990113B- - L-TRE	vol-infl.ca	LS6-RS4	NO - NC						
44	19990120A	8408	Not compl	NO - IP						
45	19990120B L	8408	G1	NO - WP						y
46	19990121A R	8408	G1	YES	TN	TN	4	TN	FC	y
47	19990121B R	8408	G1	NO - WP						y
48	19990121C	8408	LS1-RS1	PENDING					*cancelled biopsy only F/U in 6 mths*	
49	19990122A L	8408	S4	YES	INDET	TN	3	TN	FC	y
50	19990122A-R	8408	G1	YES	TN	TN	3	TN	FC	y
51	19990125A	8408	LS2-RS2	PENDING						
52	19990127A R	8408		YES	TN	TN	3	TN	Fibroadenoma	y
53	19990127B L	8408	G1	YES	FP	FP	4A	FP	FC+LS in one lobule	y
54	19990128A R	8408	G1	YES	FN	FN	5	FN	FA+DCIS (4mm)	y
55	19990201A L	8408	EUG	NO - EUG						
56	19990203A R	8408	G1	NO - WP						
57	19990203B - H-MAL	8408	EUG	NO - EUG						
58	19990203C R	8408	G1	YES	TN	TN	3	TN	SA	y
59	19990204A R	8408	EUG	NO - EUG						
60	19990204B R	8408	G1	YES	FP	FP	3	FP	FC	y
61	19990208A L	8408	EUG	NO						
62	19990209A L	8408	G1	YES	FN	TP	5	TP	DCIS	y
63	1990209B	8408		PENDING					*cancelled biopsy only F/U in 6 mths*	
64	19990209C L	8408	S3	YES	INDET	FP	4	FP	FF + PT	y
65	19990209D R	8408	EUG	NO - EUG						
66	19990210A L	8408	EUG	NO - EUG						
67	19990210B-R - I-KAT	8408	G1	YES	TP	TP	4A	TP	ID	y
68	19990210C L	8408	EUG	NO - EUG						y
69	19990216A R	8408	G1	NO - WP						y
70	19990217A R	8408	S2	YES	TN	TN	4	TN	FA (4mm)	y
71	19990218A-R - M-HAL	8408	S6	NO-WP						y
72	19990222A-L - L-SAN	8408	EUG	NO-EUG						
73	19990222B-L - G-BLU	8408	S2	NO-WP-WI						y
74	19990223A-L - A-ROG	8408	S2	YES	FP	FP	3	FP	FF	y
75	19990223B-L	8408	S3	YES	INDET	TP	4	TP	Invasive ductal with tubular featues	Y
76	19990224A-R - L-ALB	8408	EUG3	NO - EUG						y
77	19990225A-L - M-HAR	8408	E1	NO - WP,WI						y
78	19990301A-R - B-UBI	8408	S2	YES	TN	TN	3,4	TN	Lactacional activity+microcals	y
79	19990301B-L - A-MOR	8408	S2	NO-WP-WI						y
CP	**Patient ID**	**Protocol**	**Press. P**	**Acceptable**	**Blind**	**Adjunct**	**BiRads**	**Unblind**	**Biopsy**	**S. conf**
80	19990302A-R - C-COL	8408	G1	YES	FN	FN	5	FN	ID	

81	19990302B R	8408	G1	YES	TN	TN	3	TN	FF	y
82	19990302C-L - M-TOR	8408	S4	YES	TN	TN	4A	TN	CD+focal atypia+microc+vasculitis sm. Vessels	
83	19990302D-R - E-WEI	8408	G1	YES	TN	TN	4A	TN	FC+ALH+ADH+DH	
84	19990303A-L - G-JOH	8408	S3	YES	INDET	FP	4A	FP	ADH+FC(prolif)+microc	y
85	19990303B-L - E-SIL	8408	G1	YES	TN	TN	3	TN	Duct dilation with microcal.	y
86	19990309A-R - E-KAS	8408	S3	YES	TN	TN	4A	TN	FA	y
87	19990312A - R-PEN			PENDING						
88	19990312B-R - A-PEG	8408	S2	YES	TN	TN	3,4	TN	FC+FF+microcal.	y
89	19990316A-R - M-BRU	8408	G1	YES	FP	FP	3	FP	FF+FC+AD+DH	y
90	19990316B-R - M-MCG	8408	G1	YES	TN	TN	4A - 4B	TN	RS, SA, FA	y
91	19990323A			PENDING						
92	19990324A-R - L-LES	8408	S3	YES	TN	TN	4A	TN	CD	y
93	19990325A-L	8408		YES		FN				
94	19990325B-R	8408		YES		TN				
95	19990325C			PENDING						
96	19990326A			PENDING						
97	19990329A-L - G-DAV	8408	805	YES	INDET	NS	4A	NS	FC+microcal+sclerosed papilloma	
98	19990330A-R - A-FRA	8408	805	YES	INDET	INDET	4A	INDET	DE+FC+FF+microcal.+FA	y
99	19990330B-R	8408		YES		YN				
100	19990401A-R - B-KIN	8408	G1	YES	FP	FP	4	FP	FF+FC	
101	19990401B-R - A-CHO	8408	G1	NO-MV						y
CP										
102	19990405A-R - S-LOV	8408	S3	YES	INDET	TN	3	TN	FF+FC	
103	19990406A-R - C-TES	8408	s2	YES	NS	INDET	5	INDET?	DS	
104	19990406B-L - W-FOG	8408	G1	YES	FP	FP	4A	FP	DE+FA+microc.	y
105	19990406C-L - A-WHI	8408	S3	NO-WI						y
106	19990407A-R - P-MOU	8408	G1	YES	TN	TN	4B	TN	FC non-proliferative	
107	19990412A-R - P-LAF	8408	G1	PENDING					awaiting cc location of lesion	
108	19990412B			PENDING						
109	19990413A			PENDING						
110	19990416A- -K-ATH	8408		PENDING						
111	19990419A			PENDING						
112	19990421A-L - M-DIA	8408	S5	YES	TN PR	TN PR	4A	FP	SA+microc.	
113	19990421B-R - S-COR	8408	G1	YES	FP	FP	4A	FP	FC+FA+SA	
114	19990422A-L - E-WEI	8408	G1	YES	TN	TN	4A	TN	FN	
115	19990422B-L - R-RIC	8408	S3	YES	TN	TN	US	TN	FA	Y
116	19990426A			PENDING						
117	19990426B			PENDING						
118	19990427A-R - A-AAR	8408	S3	YES	NS	FN	5		DCIS+ID	
CP	**Patient ID**	**Protocol**	**Press. P**	**Acceptable**	**Blind**	**Adjunct**	**BiRads**	**Unblind**	**Biopsy**	**S. conf**
119	19990427B-R - NO-UTT	8408	G1	YES	TN	TN	4A	TN	FA+FC+LS+microcal	
120	19990428A			PENDING						

121	19990428B			PENDING						
122	19990503A			PENDING						
123	19990504A			PENDING						
124	19990506A			PENDING						
125	19990506B - L-SAR	1130B+C37		PENDING						
126	19990510A			PENDING						
127	19990510B			PENDING						
128	19990511A			PENDING						
129	19990511B			PENDING						
130	19990512A			PENDING						
131	19990513A			PENDING						
132	19990514A									
133	19990514B			PENDING						
134	19990517A			PENDING						
135	19990518A			PENDING						
136	19990518B			PENDING						
137	19990519A			PENDING						
138	19990519B			PENDING						
139	19990520A			PENDING						
140	19990520B			PENDING						
141	19990524A			PENDING						
142	19990525A-L - I-REY	8408	S2	YES	TN	TN	3	TN	FA	
143	19990527A-R	8408		YES		TN				
144	19990527B-L	8408		NO-MV						
145	19990527C-R	8408		NO-MV						
146	19990601A			PENDING						
147	19990602A			PENDING						
148	19990603A			PENDING						
149	19990603B			PENDING						
150	19990603C - VOL			PENDING						
151	19990615A			PENDING						
152	19990615B-L - D-MES	8408	G1	YES	TN	TN	4A	TN	Intraductal papilloma	
153	19990616A-R - M-TAV	8408	G1	YES	~~TN~~ FP	~~TN~~ FP	3	FP	FC+microcal	
154	19990616B-L - M-IZS	8408	G1	YES	TP	TP	4B	TP	DC+ID	
155	19990617A									
156	19990621A									
157	19990621B									
158	19990621C									
CP	**Patient ID**	**Protocol**	**Press. P**	**Acceptable**	**Blind**	**Adjunct**	**BiRads**	**Unblind**	**Biopsy**	**S. conf**
159	19990623A-L - R-NIV	8408	G1	YES	TN	TN	4A	TN	FC	
160	19990623B-R - NO-BUC	8408	G1	YES	FP	FP	4A	FP	FC	
161	19990625A			NO-VOLUNT						

162	19990625B			NO-VOLUNT						
CO										
163										
164										
165										
166										
167										

COLUMBIA						
Scan Tracking						
ID	EXCLUDED	ACCEPT	PATHOLOGY	AGE	RACE	INTERPRETATION
June-00						
06-01A	11	99	Benign	61	HW	
06-01C	11	99	Benign	35	HB	
06-05A	0	0	Benign	61	HW	TN
06-05B	0	26	Benign	66	HW	
06-07A	0	0	Benign	71	W	TN
06-07B	11	99	Benign	35	HB	
06-07C	26	99	NK		AA	
06-08A	8	99	Benign	52	W	
06-08B	0	0	Benign	50	HW	TN
06-08C	0	27	Benign	64	W	
06-08D	0	30	Benign		W	
06-08E	0	26	Malignant		HW	
06-12A	0	0	Benign	49	W	TN
06-12B	0	0	Benign	56	HW	TN
06-13A L	0	0	Benign	40	HW	TN
06-13B R	0	0	Benign	40	HW	TN
06-14B	0	0	Benign	63	HW	FP
06-15A	26	99	NK		HB	
06-19A	2	99	Benign	39	HW	
06-20A					AA	
06-21A	0	0	Malignant	44	HW	TP
06-22A	0	0	Benign	82	W	TN
06-22B	0	0	Benign	48	HB	FP
06-27A	0	26	Benign	64	W	
06-27B					HW	
06-28A	0	0	Benign	52	HW	FP
06-29A	6	99	Malignant		W	
06-29B	0	0	Benign	50	HW	TN
JUNE TOTALS:						
TOTAL SCANS:						
ACCEPTABLES		(12 benign/1 malignant)				
UNACCEPTABLES						
EXCLUDED PTS						
TBI						

July-00						
07-03A	6	99	Benign	46	W	
07-05A	22	99	NK		W	
07-05B	19	99	NK	68	HB	
07-05C	0	17	Benign	59	W	
07-06A L	0	0	Benign	65	HW	FP
07-06A R	0	0	Benign	65	HW	TN
07-11A	0	17	Benign	37	W	
07-11B	11	99	Benign	57	W	
07-13A	0	21	Malignant	54	W	
07-13C	11	99	Benign	38	OTHER	
07-17A	12	99	NK		W	
07-17B	1	99	Benign	43	HW	
07-17C	0	11	Malignant	46	HB	
07-18A L	0	10,11	Benign	49	W	
07-18B R	0	10,11	Benign	49	W	
07-24A	0	11	Benign	38	W	
07-24B				61	W	
07-26A	0	11	Benign	73	OTHER	
07-27B	6	99	Malignant	81	AA	
07-28A	0	0	Benign	57	W	TN
07-31A	6	99	Malignant	66	W	
JULY TOTALS:						
TOTAL SCANS:						
ACCEPTABLES		3 benign				
UNACCEPTABLES						
EXCLUDED PTS						
TBI						

August-00						
08-01A	1	99	Malignant	64	W	
08-01C	11	99	NK	51	W	
08-01D	0	0	Benign	53	W	FP
08-02A	0	0	Benign	69	HW	TN
08-02B	0	0	Malignant	46	W	TP
08-02C	0	0	Benign	44	HB	FP
08-04A	0	21	Benign	40	HB	
08-09A	26	99	Benign	36	W	
08-09B	1	99	Malignant	76	W	
08-09C	0	0	Benign	54	HW	TN
08-10A	0	0	Malignant	63	W	TP
08-10B L	0	13	Benign	55	W	
08-10C R	6	99	Benign	55	W	
08-14A	0	0	Benign	48	W	TN
08-14B					HB	
08-15A	0	0	Benign	50	AA	TN
08-15B	0	0	Benign	55	W	FP
08-16A	11	99	Benign	36	HB	
08-17A	1	99	Malignant	63	W	
08-17B	0	0	Malignant	68	W	TP
08-21A	0	0	Benign	48	HW	TN
08-21B	10	99	Atypia	49	ASIAN	
08-21C					W	
08-21D				80	HB	
08-21E	0	21	Benign	60	W	
08-23A	4	99	Malignant	68	HW	
08-28A	11	99	Benign	69	W	
08-29A	3	99	Benign	51	W	
08-29B	0	0	Benign	43	W	TN
08-29C	0	0	Benign	49	HW	TN
08-31A	0	0	Benign	61	HW	TN
08-31B	0	0	Benign	51	W	TN
08-31C	2	99	Benign	40	HW	
08-31D	0	0	Malignant	82	HB	TP
08-31E	11	99	Benign	40	HW	
08-31F	6	99	Malignant	54	HW	
08-31G	0	21	Benign	42	HW	
08-31H	4	99	Benign	47	W	
AUGUST TOTALS:						
TOTAL SCANS:						
ACCEPTABLES		(12/4)				
UNACCEPTABLES						
EXCLUDED PTS						
TBI						

September-00						
09-05A	4	99	Malignant	80	W	TN
09-05B	0	0	Benign	52	W	TN
09-05C	0	0	Benign	60	W	
09-05D	11	99	NK	45	HB	
09-06A	6	99	Benign	79	W	
09-06B	0	0	Benign	43	W	FP
09-07A	0	0	Malignant	74	HW	TP
09-07B	0	21	Benign	69	AA	
09-11A	0	0	Benign	54	ASIAN	TN
09-11B	0	0	Malignant	68	HW	TP
09-11C	0	0	Benign	70	W	TN
09-13A					HW	
09-13B					HW	
09-14A	0	0	Malignant	48	W	TP
09-14B	0	21	Malignant	50	W	
09-14C	7	99	Benign		W	
09-14E	0	0	Benign	46	HW	FP
09-14F(8)	4	99	Benign	42	HB	
09-18A	0	0	Malignant	80	W	FN
09-18B	0	0	Benign	42	HB	FP
09-19A	6	99	Malignant	74	W	
09-19B					HW	
09-20A	0	0	Malignant	67	W	TP
09-20B					W	
09-20C	0	0	Malignant	75	W	FN
09-21A	0	0	Benign	63	HB	FP
09-21B	0	16	Benign	51	W	
09-25A	11	99	Benign	45	W	
09-28A	11	99	Benign	56	W	
09-28B	0	0	Benign	57	HW	FP
SEPTEMBER TOTALS:						
TOTAL SCANS:						
ACCEPTABLES		(9/6)				
UNACCEPTABLES						
EXCLUDED PTS						
TBI						
OVERALL TOTALS						
TOTAL SCANS:		117				
ACCEPTABLES		47(36 benign/11 malignant)				
UNACCEPTABLES		20				
EXCLUDED PTS		40				
TBI	TBI	10				
	AVERAGE AGE	55.68				

PATIENT SCREENING EXCLUSION CODES

CLINICAL

01 Outside of BI-RADS categories 3 and 4
02 Not all records available at site for review
03 Biopsy at another facility
04 Post-menopausal with a palpable lesion
05 Pregnant or lactating
06 Breast surgery in ipsilateral breast
07 Biopsy of ipsilateral breast (core or excisional) within past three months
08 Surgical clips or scarring in or on ipsilateral breast
09 Patient refused consent.

IMAGING

10 Small breasts that, in the judgment of the technologist, cannot be properly positioned
11 Lesion is subareolar or located where it cannot be properly illuminated (e.g. lesions visible on MLO view that *cannot also* be visualized on the CC view)
12 Patient unable to stand still

CODES FOR UNACCEPTABLE SCANS

BREAST POSITIONING:

13 Breast too small
14 Soft holder not closed properly
15 Non-symmetrical positioning
16 Not enough breast tissue in holder

ILLUMINATION

17 Size of illumination too small
18 Size of illumination too large
19 Intensity too high
20 Intensity too low
21 Inadequate illumination in area of pathology
22 Ambient light leakage

DEVICE RELATED

23 Computer error
24 Air leakage
25 Other error: Copy error message number from screen
26 Other Device Related: Describe

PATIENT RELATED

27 Excessive patient movement
28 Patient complaint/refusal after scan has started
29 Other Patient Related: Describe

OTHER

30 Other: Describe